UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,830	08/26/2002	Crisanto Gutierrez-Armenta	BTGI-0025	2262

34141 7590 07/28/2006

COZEN O' CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,830	GUTIERREZ-ARMENTA ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,12-24 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-6, 12-24 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application on May 5, 2006 after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 7, 2006 has been entered.

Claims 4, 7-11 and 25-46 are cancelled.

Claims 1, 5, 12, 22 and 47 are currently amended.

Claims 1-3, 5-6, 12-24 and 47 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-3, 5-6, 12-13, 15, 22-24 and 47 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant maintains that a sufficient description of the claimed invention has been provided. Applicant points to claim limitations that recite the protein or peptide comprises one or more of the following structural features common to DP proteins and set forth in the specification: a) the DNA binding domain, b) the heterodimerization domain, and c) the nuclear localization signal, which are features common to the genus and constitute a substantial portion of the genus. Applicant also points to claim limitations that recite functional limitations such as dimerization with an E2f protein to increase or decrease E2F activity in a plant cell. Applicant additionally points to claim limitations that recite percent homology to a specific amino acid sequence. Applicant also points out that a single disclosed specie may adequately support the description of a genus, and Applicant maintains that the disclosure of additional species is not warranted here because the claims recite common attributes and features of the elements possessed by the members in view of the specie disclosed. Applicant further points out that the written description requirement is met so long as the invention is described in the specification as broadly as it is claimed. (reply pages 10-11)

Applicant's arguments are unconvincing. The invention is not described in the specification as broadly as it is claimed. The recitation of structure and function in the claims does not describe the claimed invention because the recited genus has not been described. In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus, as Applicant has described only a single specie. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508,

1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). Unpredictability in the results obtained from species other than those specifically enumerated (SEQ ID NO:2) was evidenced by Hiebert S. W. et al., Magyar Z. et al., Dynlacht B.D. et al., Sawado T et al., Wu CL et al. and Mariconti L. et al. as set forth at pages 10-12 of the office action mailed March 15, 2005.

Claims 1-3, 5-6, 12-13, 15-24 and 47 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant points out that claims 12, 13, 15-24 and 47 are directed to compounds and not methods, and that undue experimentation is not required to make the claimed compounds, as nucleic acids are routinely made by those skilled in the art (reply page 12).

The Examiner maintains that Applicant's comments are inapposite to the outstanding rejection, which is not predicated on the ability of those skilled in the art to make nucleic acid compounds.

Applicant also maintains that any use of the compounds is sufficient for the purpose of their enablement, that the claimed compounds can be used to express a protein, to detect nucleic acid sequences, or as primers for DNA amplification, and that undue experimentation is not required for any of these uses (reply page 12).

The Examiner maintains that the asserted uses are not enabled, as the specification does not provide sufficient guidance with respect to how to use any particular protein expressed from any of the claimed sequences, or with respect to how to use any of the claimed sequences to detect any particular nucleic acid sequences, or with respect to how to use any of the claimed sequences to amplify any particular DNA fragment.

Applicant further argues that argues that Gillespie D. does not teach or suggest that Applicant's claimed invention does not work or would require undue experimentation, as the principals set forth in Gillespie D. were well known to those of skill in the art prior to Applicant's filing date, and the optimization of hybridization conditions was routinely practiced. Applicant also maintains that the selection of probes does not involve the examination of a myriad of possibilities as it is limited by the sequence from which the probe is derived (SEQ ID NO:1) (reply pages 13-14)

Applicant's arguments are unconvincing. The outstanding rejection was not predicated on a failure to provide guidance with respect to the general practice of techniques that are known to and/or within the abilities of those skilled in the art. The outstanding rejection was predicated in part on a failure to provide guidance with respect to the specific practice of such techniques, i.e. with respect to which specific nucleotide sequences to use as DNA probes, the conditions for

their use, and the specific targets that can be detected using these probes. Such guidance is necessary because the conditions for using a sequence as a probe are unpredictable as set forth in Gillespie D. Absent such guidance one skilled in the art would have to test each of the myriad sequences encompassed by the claims under a variety of different conditions in order to determine which probe sequences are useful for the detection of particular target sequences and which are not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation. Further, the selection of probes does involve the examination of a myriad of possibilities, because the claims encompass multiple nucleotide sequences that differ in both primary sequence and length (10 or more contiguous nucleotides or at least 18 contiguous nucleotides of SEQ ID NO:1, which consists of 1089 contiguous nucleotides), and because the selection of a probe or primer also requires the selection of target sequences.

Applicant notes that claims 1-3, 5 and 6 recite that the proteins or peptides encoded by the nucleic acid comprise at least one structural domain of known function that has been demonstrated as being present in other DP proteins, and also points out that the specification also teaches ample methods for verifying the activity of such proteins, such that no undue experimentation would be required to practice the claimed invention (reply page 14).

Applicant's arguments are unconvincing. The outstanding rejection was not predicated on a failure to provide guidance with respect to the general practice of techniques for verifying DP protein activity that are known to and/or within the abilities of those skilled in the art. The outstanding rejection was predicated in part on a failure to provide guidance with respect to the specific practice of such techniques, i.e. with respect to which sequences to make and test, and

with respect to which functional assays to apply to which sequences, in order to discriminate between those sequences that function as desired and those that do not. Absent such guidance, one skilled in the art would have to isolate from undisclosed sources and/or synthesize each of the myriad sequences encompassed by the claims and then determine the specific function of each in order to discriminate between those sequences that function as desired and those that do not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation. Further, reciting that the proteins or peptides encoded by the nucleic acid comprise at least one structural domain of known function that has been demonstrated as being present in other DP proteins does not provide the required guidance, as the functional contribution of a domain to the protein that comprises it is context dependent.

Applicant also maintains that the fact that DP proteins may have many different functions is wholly irrelevant in determining whether one skilled in the art can practice the claimed invention without undue experimentation. Applicant argues that the variability of function observed for DP proteins in nonplant cells as set forth in Hiebert S. W. et al., Dynlacht B.D. et al., Sawado T et al. and Wu CL et al. is irrelevant to determining whether undue experimentation is required to carry out the claimed method in plant cells, and Applicant maintain that they are unable to locate any portion of these references that teach or suggest that observations of different proteins in a different kingdom are what would also be expected in plants. (reply page 15)

Applicant's arguments are unconvincing. The variability of function observed for different types of nonplant DP proteins in nonplant cells is relevant to determining whether

undue experimentation is required to carry out the claimed method in plant cells, because both the cell cycle and the proteins whose activity is required for its progression are conserved across the eukaryotic kingdoms, and because variability of structure and function have also been observed for different types of plant DP proteins. The cited references need not teach or suggest that observations pertaining to animal DP proteins are what would also be expected of plant DP proteins, as the conservation of both the cell cycle and the proteins whose activity is required for its progression is well established in the prior art.

Applicant additionally argues that Magyar Z. et al. and Mariconti L. et al. do not teach or suggest that Applicant's claimed invention does not work or would require undue experimentation, as Magyar Z. et al. and Mariconti L. et al. are directed to sequences encoding DP proteins obtained from *Arabidopsis thaliana*, and are silent with respect to Applicant's claimed invention which makes use of sequences encoding DP proteins obtained from wheat (reply pages 15-16).

Applicant's arguments are unconvincing. Neither Magyar Z. et al. nor Mariconti L. et al. were cited for any specific teachings with respect to the functionality of or use of wheat DP proteins. Both Magyar Z. et al. and Mariconti L. et al. were cited to support the general assertion that the effect of expressing in a cell a DP protein, alone or in combination with an E2F protein, is unpredictable, since different members of both the DP protein family and the E2F protein family vary with respect to their specific functions, and with respect to how they function when expressed independently and when coexpressed. Given that the effect of expressing in a cell a DP protein, alone or in combination with an E2F protein, is unpredictable, and given that the

genus of sequences recited in the claims appear to encode polypeptides that belong to the DP family of proteins, the effect of expressing in a cell any member of the genus of sequences recited in the claims is also unpredictable. Furthermore, the rejected claims are not limited to the use of sequences encoding DP proteins obtained from wheat.

Applicant also argues that Sandler S.J. et al., van der Krol A.R. et al. and Waterhouse et al. do not teach or suggest that Applicant's claimed invention does not work or would require undue experimentation, as the principals set forth in Sandler S.J. et al., van der Krol A.R. et al. and Waterhouse et al. were well known to those of skill in the art prior to Applicant's filing date, and the general principals of antisense sequence construction and use in plants is broadly appreciated in the art. Applicant also points to Shewmaker C.K. et al. (US Patent No. 5,107,065, issued April 21, 1992) cited in the specification which teaches the general principals of the construction of antisense compounds (reply page 16).

Applicant's arguments are unconvincing. The outstanding rejection was not predicated on a failure to provide guidance with respect to the general practice of techniques that are known to and/or within the abilities of those skilled in the art. The outstanding rejection was predicated in part on a failure to provide guidance with respect to the specific practice of such techniques, i.e. with respect to which nucleotide sequences to express in a plant as antisense transcripts, or how to express them such that plant growth, gene expression, DNA replication, cell cycle progression, differentiation and development could be controlled in a particular manner. Such guidance is necessary because methods for inhibiting the expression of endogenous genes using antisense technology are unpredictable as set forth in Sandler S.J. et al., van der Krol A.R. et al.

and Waterhouse et al. Absent such guidance one skilled in the art would have to test each of the myriad sequences encompassed by the claims for its specific effect on plant growth, gene expression, DNA replication, cell cycle progression, differentiation and development in order to discriminate between those sequences that function as desired and those that do not. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation. Furthermore, the disclosure of the general principals of the construction of antisense compounds by Shewmaker C.K. et al. does not provide guidance with respect to the specific practice of such techniques using the nucleotide sequences encompassed by the claims.

Claim 1 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "controlling", for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant maintains that the question of how these features are controlled is irrelevant, as persons of ordinary skill in the art would have no difficulty in determining whether plant growth, gene expression, cellular DNA replication, cell cycle progression and differentiation and development were controlled by carrying out the claimed method. Applicant also maintains that the Examiner provides no evidence to support the conclusion that persons of ordinary skill in the art would be unable to determine whether plant growth, gene expression, cellular DNA replication, cell cycle progression and differentiation and development were controlled by carrying out the claimed method. Applicant additionally points out that the "many ways" in which plant growth, gene expression, cellular DNA replication, cell cycle progression and

differentiation and development may be controlled have been explained buy the Examiner. (reply pages 17-18).

Applicant's arguments are unconvincing. The question of the way in which the recited features are controlled is relevant. Additionally, it was not asserted that persons of ordinary skill in the art would be unable to determine whether plant growth, gene expression, cellular DNA replication, cell cycle progression and differentiation and development were controlled by carrying out the claimed method. It was asserted that persons of ordinary skill in the art would have difficulty in determining what subject matter is or is not within the scope of the claims because the recited characteristics may be controlled in many different ways, because the way in which the recited features are controlled cannot be discerned from the elements recited in the claims. Accordingly persons of ordinary skill in the art would not know which aspect of plant growth, gene expression, cellular DNA replication, cell cycle progression or differentiation and development to evaluate in order to determine what subject matter is or is not within the scope of the claims. ways in which plant growth, gene expression, cellular DNA replication, cell cycle progression and differentiation and development may be controlled are both numerous and known, and may include but are not limited to increases or decreases in plant growth rate or changes in plant growth conditions, increases or decreases in the expression of specific genes or changes in the number, type, location and timing of the expression of specific genes, increases or decreases in the rate of DNA replication or cell cycle progression or differentiation, or changes in the timing of DNA replication or cell cycle progression or differentiation, or changes in the number, type, and location of cells in which DNA replication or cell cycle progression occurs, or differentiation, etc.

Claim 1 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "increase or decrease", for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant maintains that the phrase is as clear as can be, as one skilled in the art would be able to determine whether the E2F activity increases or decreases. Applicant also maintains that whether or not the claimed method leads to an increase or a decrease in E2F activity is not the issue, as the method can be carried out using any number of nucleic acid molecules, some of which can lead to an increase in E2F activity and some of which can lead to a decrease. Applicant additionally maintains that the method should not be thought of as a single method, since it can be carried out with more than on type of nucleic acid compound (reply page 18).

Applicant's arguments are unconvincing. The recitation of "increasing or decreasing" is indefinite in the context of the claim language because it is unclear how a single method could both increase or decrease E2F-dimerization partner (DP) protein activity in a plant cell, and there are insufficient elements recited in the claims to indicate that the claimed method would produce such a result. Additionally, the claimed method must be thought of as a single method, as the claim is directed to "a" method. Further, methods that employ structurally distinct compounds that produce different effects are properly considered to be independent and distinct inventions.

Claim 5 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "altering", for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant points out that the term altering has been amended where appropriate, and maintains that "alteration of the DP protein level and E2F-DP transactivation properties" does not lack clarity, as an alteration in the level of a protein or E2F-DP transactivation properties can only be in the sense of increasing or decreasing. Applicant also maintains that whether or not the claimed method leads to an increase or a decrease in DP protein level or E2F-DP transactivation properties is not the issue, as the method can be carried out using any number of nucleic acid molecules, some of which can lead to an increase in DP protein level or E2F-DP transactivation properties and some of which can lead to a decrease. Applicant additionally maintains that the method should not be thought of as a single method, since it can be carried out with more than on type of nucleic acid compound (reply page 19).

The rejection is maintained as claim 5 still requires alteration of the plant DP protein level and E2F-DP transactivation properties. It is unclear in what way plant DP protein level and E2F-DP transactivation properties are altered, as plant DP protein level and E2F-DP transactivation properties may be altered in more than one way. Further, the phrase "alteration of the DP protein level" does lack clarity even though an alteration in the level of a protein can only be in the sense of increasing or decreasing, because neither claim 5 nor claim 1 from which it depends recites a specific method that would result in both an increase and a decrease in the level of plant DP protein when practiced. Additionally, the claimed method must be thought of as a single method, as the claim is directed to "a" method. Further, methods that employ structurally

distinct compounds that produce different effects are properly considered to be independent and distinct inventions.

Claim 5 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "modulation", for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant points out that the term altering has been amended where appropriate, and maintains that "modulation of E2F-DP DNA-binding activity" does not lack clarity, as modulation of E2F-DP DNA-binding activity can only be in the sense of increasing or decreasing. Applicant also maintains that whether or not the claimed method leads to an increase or a decrease in E2F-DP DNA-binding activity is not the issue, as the method can be carried out using any number of nucleic acid molecules, some of which can lead to an increase in E2F-DP DNA-binding activity and some of which can lead to a decrease. Applicant additionally maintains that the method should not be thought of as a single method, since it can be carried out with more than on type of nucleic acid compound (reply page 19).

The rejection is maintained as claim 5 still requires modulation of E2F-DP DNA-binding activity. It is unclear in what way E2F-DP DNA-binding activity is modulated, as the binding of a protein to DNA may be modulated in more than one way, and the nature of the modulation cannot be discerned from the current claim language. Further, the phrase "modulation of E2F-DP DNA-binding activity" does lack clarity even though the modulation may be in the sense of increasing or decreasing, because neither claim 5 nor claim 1 from which it depends recites a

specific method that would result in both an increase and a decrease in E2F-DP DNA-binding activity when practiced. Additionally, the claimed method must be thought of as a single method, as the claim is directed to "a" method. Further, methods that employ structurally distinct compounds that produce different effects are properly considered to be independent and distinct inventions.

Claim 5 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "increasing or decreasing".

Applicant maintains that the phrase is not indefinite, as the method can be carried out using any number of nucleic acid molecules, some of which can lead to an increase in binding of DP to E2F and some of which can lead to a decrease. Applicant additionally maintains that the method should not be thought of as a single method, since it can be carried out with more than on type of nucleic acid compound (reply page 20).

Applicant's arguments are unconvincing. The recitation of "increasing or decreasing" is indefinite in the context of the claim language because it is unclear how a single method could both increase or decrease binding of DP to E2F, and there are insufficient elements recited in the claims to indicate that the claimed method would produce such a result. Additionally, the claimed method must be thought of as a single method, as the claim is directed to "a" method. Further, methods that employ structurally distinct compounds that produce different effects are properly considered to be independent and distinct inventions.

Claim 6 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "modification" and "activity", for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant maintains that the phrase "modification of levels or activity of plant E2F and/or plant Rb" is not unclear, but is broadly drafted to include any modification of the levels or activity of plant E2F or plant Rb or plant Rb (reply page 20)

Applicant's arguments are unpersuasive. The phrase "modification of levels or activity of plant E2F and/or plant Rb" is unclear in the context of the current claim language. The drafting of the claim to include any modification of the levels or activity of plant E2F or plant Rb or plant Rb renders the claim indefinite because neither claim 6 nor claim 1 from which it depends recites a specific method that would result in any modification of the levels or activity of plant E2F or plant Rb or plant Rb when practiced.

Claim 6 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "increased or decreased", for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant maintains that the phrase is not indefinite, as the method can be carried out using any number of nucleic acid molecules, some of which can lead to an increase in DP protein activity and some of which can lead to a decrease. Applicant additionally maintains that the

method should not be thought of as a single method, since it can be carried out with more than on type of nucleic acid compound (reply page 20).

Applicant's arguments are unconvincing. The recitation of "increased or decreased" is indefinite in the context of the claim language because it is unclear how a single method could both increase or decrease DP protein activity, and there are insufficient elements recited in the claims to indicate that the claimed method would produce such a result. Additionally, the claimed method must be thought of as a single method, as the claim is directed to "a" method. Further, methods that employ structurally distinct compounds that produce different effects are properly considered to be independent and distinct inventions.

Claim 12 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "modulation", for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant maintains that the phrase is not indefinite, as one skilled in the art would understand modulate to mean increases or decreases. (reply page 20).

Applicant's arguments are unconvincing. The recitation of "modulation" is indefinite in the context of the claim language because it is unclear how a single method could both increase or decrease E2F binding to E2F transcription factor binding sites in plant DNA, and there are insufficient elements recited in the claims to indicate that the claimed method would produce such a result.

Claim Rejections - 35 USC § 101 and 35 USC § 112

Claims 1-3, 5-6, 12-24 and 47 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for the reasons of record.

Claims 1-3, 5-6, 12-24 and 47 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant maintains that activity for the protein comprising SEQ ID NO:2 has been established through a combination of sequence similarity and functional evidence as presented in the application, for example in Examples 1, 5, 6, 7 and 9 and Figures 2 and 3. Applicant maintains that the specification provides ample sequence similarity data to indicate that SEQ ID NO:2 is a DP protein, and in this regard Applicant points in particular to Example 1 which discloses that SEQ ID NO:2 shares several conserved motifs with animal DP sequences and inrteacts with a plant E2F protein. Applicant also points in particular to Example 9 in this regard which discloses analysis of the domain organization of SEQ ID NO:2 and its amino acid sequence homology to animal DP sequences which reinforce the idea that SEQ ID NO:2 is a member of the DP family of proteins. Applicant further points in particular to Examples 5-7 in this regard which disclose that SEQ ID NO:2 binds an E2F protein and modulates its binding to DNA. Applicant also maintains that it is not the properties of SEQ ID NO:2 per se that provide a

real world use for the protein, as the combination of sequence similarity data and functional studies clearly establish that SEQ ID NO:2 is a DP protein, and DP proteins have a variety of specific and substantial utilities. In this regard Applicant additionally points to the teaching of Lowe K. et al., PCT publication WO 00/47614, published 17 August 2000, as teaching real world uses for DP proteins. (reply pages 7-9)

The Examiner maintains that the combination of sequence similarity and functional evidence presented in the instant application does not establish a specific and substantial utility for the protein comprising SEQ ID NO:2. That the amino acid sequence of SEQ ID NO:2 possesses characteristics sufficient to classify it in the DP family of proteins does not establish a utility for SEQ ID NO:2 that is both specific and substantial, as neither the specification nor the prior art of record indicate that the possession of the common characteristics disclosed is necessary and sufficient for SEQ ID NO:2 to exhibit any particular property having a real world use that is associated with a known DP protein family member. Further, it is the properties of SEQ ID NO:2 per se that determine whether SEQ ID NO:2 has a real world use, as the combination of sequence similarity data and functional studies are not sufficient to establish that SEQ ID NO:2 has any specific and substantial utility known to be associated with a DP protein.

Claim Rejections - 35 USC § 102

Claims 17, 18, 19 and 20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Gillaspy G.E et al., GenEmbl Accession No. U39059, 18 November 1996, for the reasons of record.

Applicant's arguments filed March 7, 2006 have been fully considered but they are not persuasive.

Applicant points out that a sequence alignment of the Gillaspy sequence and SEQ ID NO:1 shows only that the two sequences possess 52 contiguous adenosines in common in the poly A tail and 8 other bases in common. Applicant maintains that the Gillaspy sequence does not represent a nucleic acid probe because it has only limited GC content and does not appear likely to act as a probe at a reasonable stringency; nor would it represent a suitable primer because it does not appear likely to bind the target at temperatures normally used for specific amplification. Applicant also maintains that one skilled in the art would be very unlikely to select a probe that contains a sequence that is quite clearly not in any way specific to a particular sequence. (reply page 6)

Applicant also maintains that they are not reciting a nucleic acid molecule in the rejected claims, but rather a probe or primer, which are distinguishable as a subtype of nucleic acid molecule by one skilled in the art as having inherent features which render them useful. Applicant additionally maintains that one skilled in the art would be very unlikely to select a probe that contains 52 base polyA sequence that would clearly not be specific to a plant DP sequence (reply pages 6-7).

Applicant's arguments are unpersuasive. In response to applicant's argument that the reference fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., ability to hybridize to a specific target sequence under conditions of specified stringency and specificity for a plant DP sequence) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, a nucleic acid molecule is recited in the rejected claims, as the nucleic acid probe or primer of claim 17 comprises " a double or single stranded DNA molecule comprising 10 or more contiguous nucleotides", and the probes and primer of claims 18 to 20 comprise nucleotide bases.

Gillaspy G.E et al. anticipate the claimed invention because Gillaspy G.E et al. teach a DNA sequence consisting of 60 contiguous nucleotides of SEQ ID NO:1 that are not selected from nucleotides encoding amino acids 70 to 136. Accordingly the DNA sequence taught by Gillaspy G.E et al. comprises 10 or more contiguous nucleotides of SEQ ID NO:1 that are not selected from nucleotides encoding amino acids 70 to 136, at least 18 contiguous bases of SEQ ID NO:1, 30 to 100 contiguous bases of SEQ ID NO:1, and 10 to 20 contiguous bases of SEQ ID NO:1.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

Cynthia Collins
7/24/06